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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,011	06/11/2002	John J Bissler	CMC-151	5783

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EXAMINER

DRODGE, JOSEPH W

ART UNIT PAPER NUMBER

1723

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<p>Application No. 10/030,011</p>	<p>Applicant(s) BISSLER ET AL.</p>	
	<p>Examiner Joseph W. Drodge</p>	<p>Art Unit 1723</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 and 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 9 and 15-18 is/are rejected.
- 7) ☒ Claim(s) 10-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                     | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) ____.   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1003</u> . | 6) <input type="checkbox"/> Other:  |

NON-FINAL REJECTION

Claims 4-7 and 10-14 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and <sup>and 16</sup>9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lichtensteinn patent 4,370,983.

Lichtenstein discloses a extracorporeal blood treatment systems in which blood is removed from a patient, treated by means such hemofilters or ultrafilters, blood flow being controlled by control of various pumps and valves which are controlled by signals from controllers that are based on a combination of measured patient parameters and system parameters including flow rates (see column 6, line 40-column 7, line 18; column 8, lines 23-34 and column 11, line 29-column 12, line 7, etc.). As to adaptive control and time dependent deviations and parameters, see column 13, lines 17-37.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-3<sup>and 15</sup><sub>Λ</sub> are rejected under 35 U.S.C. 103(a) as being unpatentable over Lichtenstein in view of Roeher et al patent 5,503,624.

Claims 1-3<sup>and 15</sup><sub>Λ</sub> differ in requiring the control program to include fuzzy logic control. Such control is taught by Roeher et al, who teaches extracorporeal blood treatment and combined monitoring of patient parameters and system parameters of pressure and flows (column 3, lines 35-57) and fuzzy logic control (column 2, lines 24-49). It would have been obvious to have incorporated the fuzzy logic control of Roeher et al into the Lichtenstein system, in order to quantify the complex interacting mechanisms between the different patient parameters and system flow rates and their effects on the health and safety of the patient.

As to claim 2, Lichtenstein discloses sensing of patient blood pressures and heart rates in column 8, lines 39-46, such is also taught by Roeher et al; as to claim 3, Lichtenstein discloses ultrafiltration as one mechanism of treatment (column 4, lines 18-22).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lichtenstein in view of Kitaevich et al patent 5,211,849.

Lichtenstein also discloses temporary storage of blood removed from patients in analysis reservoirs to allow the blood to be analyzed (column 10, lines 54-63) and storage of filtrate or (blood drained from the filter) in column 30, lines 64-68 to allow the filtrate to be mixed with other infusate fluids prior to reinjection into the patient.

The claim differs in requiring monitoring of the weight of fluid in these reservoirs and such weight being incorporated into derivation of signals for controlling the blood pump(s) by the controller means. Kitaevich et al '849 teaches such weight monitoring and incorporation of derived data via signals (column 2, line 57-column 3, line 53). It would have been obvious to one of ordinary skill in the art to have augmented the controlling mechanisms of the Lichtenstein system with such monitoring of weight in the reservoirs and incorporation of data derived input signals, as taught by Kitaevich et al, to ensure ideal balancing of fluid removal and fluid replacement to the patient.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lichtenstein in view of Roeher et al and Kitaevich et al.

Claim 17 differs from Lichtenstein by the requiring of both fuzzy logic control and by requiring monitoring of the weight of fluid in the reservoirs upstream and downstream of the blood pump and blood treatment means. It would have been obvious to the ordinarily skilled artisan to have modified the Lichtenstein system by utilizing such fuzzy logic control, as taught by Roeher et al, so as to quantify the complex interacting mechanisms between the different patient parameters and system parameters including flow rates and their effects on the health and safety of the patient.

It would have also been obvious to one of ordinary skill in the art to have augmented the Lichtenstein system by monitoring the weight of fluid in the reservoirs upstream and downstream of the blood pump and treatment means and incorporated data derived input signals from such monitoring, as taught by Kitaevich et al, in order to ensure ideal balancing of fluid removed from the patient and fluid returned to the patient.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kitaevich et al patent 6,471,872 is of interest as a patent by the assignee and claiming similar subject matter, however no double patenting issue is seen at this time.

Any inquiry concerning this communication or other matters pertaining to prosecution of this application should be directed to Examiner Joseph Drodge at telephone number (703) 308-0403 Mondays through Fridays between 8:30 and 4:45. The Fax number for the examining Group is (703) 872-9306.

JWD

October 28, 2003

  
JOSEPH DRODGE  
PRIMARY EXAMINER